UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE K-V PHARMACEUTICAL COMPANY SECURITIES LITIGATION	)	Case No. 4:11-CV-01816-AGF

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION TO RECONSIDER THE SCOPE OF THE LEAVE TO AMEND PROVIDED IN THE MEMORANDUM AND ORDER

PRELIMINARY STATEMENT

On March 27, 2014, the Court issued a Memorandum and Order ("Order"; Dkt. No. 116) granting Defendants' motion to dismiss the Consolidated Amended Class Action Complaint ("Complaint"; Dkt. No. 67), but "without prejudice to Plaintiffs' filing a second amended complaint with respect to a limited issue" of whether Defendants' statements about the Company's "financial assistance program for patients who could not afford Makena at the $1,500 per injection price" were materially false and misleading. Order at 1, 21. The Court allowed Plaintiff 20 days to file a new amended complaint covering that limited subject.[1] Order at 21. Plaintiff respectfully moves, pursuant to Fed. R. Civ. P. 54(b) ("Rule 54(b)"), Fed. R. Civ. P. 60(b) ("Rule 60(b)") and the Court's inherent authority to alter its own interlocutory orders, for reconsideration of the Court's Order restricting the scope of amendment solely to the

[1] At this time, Plaintiff has no further allegations concerning the financial assistance program and does not intend to amend her allegations in that regard. Further, Plaintiff is not filing an amended complaint at this time with the new allegations because the Court denied Plaintiff leave to amend as to the issues that are the subject of this motion, and Plaintiff believes it would be improper and/or presumptuous to submit a pleading without leave from the Court.

allegations concerning the financial assistance program.[2]

Plaintiff seeks leave to file an amended complaint, which would contain, *inter alia*, the following new allegations, which are further detailed herein:

- That when the U.S. Food and Drug Administration ("FDA") does take enforcement action with regard to preventing compounding pharmacies from manufacturing drugs that have gained Orphan Drug Act ("ODA") status, typically either the FDA itself will learn of a violation or the holder of the orphan drug will notify the FDA of a violation and the FDA will send warning letters to the entity or entities in violation. Two examples of that process involved the drugs Premarin and Morphine. Here, K-V Pharmaceutical Company ("K-V") did not ask the FDA to enforce against the compounding pharmacies, but instead took it upon itself to send letters to the compounding pharmacies stating that "compounded, unapproved formulations of hydroxyprogesterone caproate injection should no longer be made by compounding pharmacies" and that the FDA's enforcement "discretion does not extend to compounding of copies or essentially copies of commercially available FDA-approved products" (¶50). Plaintiff contends that the most reasonable inference is that K-V took this step and by-passed the FDA because it knew or was substantially certain that if it asked the FDA to enforce Makena's exclusivity, the FDA would have refused to do so. This provides a strong inference of Defendants' knowledge that, contrary to their public statements, there was a substantial risk that the FDA would not enforce Makena's exclusivity;

- That Defendants were informed by CW1 that even if the FDA sought to enforce exclusivity, its ability to do so is extremely limited due to its limited resources. Therefore, even if the FDA chose to enforce exclusivity for Makena, it could not effectively stop individual, geographically widely dispersed pharmacies from compounding the drug. Thus, contrary to the import of their statements to the public, Defendants knew that they would not be able to halt most compounding of the drug as identifying violations and pursuing such efforts would not be practical or economically feasible for the

[2] The Court denied leave to amend on the other allegations based on colloquy with Plaintiff's counsel. *See* Order at 24 ("Plaintiffs suggested at oral argument that if given some time to explore the matter, they could possibly find a factual basis to support further amendment to the complaint to allege that one or more of the CWs had such knowledge."). However, Plaintiff's counsel told the Court that "with respect [to the FDA not enforcing in similar circumstances and the CW1's knowledge of such an example], could we amend, could we go back to CW-1 and get more information about his experience? I suppose we can." Tr. 62 lines 10-12. The Court did not ask how long it would take Plaintiff to make these amendments. The Court found 20 days to be a reasonable time for Plaintiff to amend certain allegations, and, therefore, Plaintiff seeks 20 days to amend the Complaint to add in the allegations discussed herein.

FDA or K-V;

- Since the filing of their motion to dismiss, Defendants have admitted the material falsity of their statements that "[W]e believe that ***the regulations and laws are very clear***. . . . FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products," and that "we also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them," *see, e.g.*, ¶48 (emphasis added), when Defendants wrote to this Court stating that: ***"[w]hether and to what extent the FDA had the discretion not to enforce exclusivity under the Orphan Drug Act remains a matter of ongoing dispute*** in the D.C. District Court Action." *See* Dkt. No. 112 ("Notice") at 1 (emphasis added). This statement is a clear concession that (1) the FDA may or may not have the discretion not to enforce exclusivity under the ODA; and (2) that Defendants could not have had a reasonable basis in fact to make the affirmative, unmitigated statement to the investing public that "the regulations and laws are ***very clear***" regarding enforcement of exclusivity under the ODA as they have now admitted those regulations are not clear at all and certainly not "very clear"; and

- That Defendants' statement that "we believe our pricing approach is supported by a very comprehensive market research plan which included all stakeholders," Order at 5, was false and misleading because, according to CWs that Plaintiff has re-interviewed or new CWs, no "comprehensive market research" was conducted by K-V to support the pricing of Makena. Rather, K-V did none of the things an elementary market research analysis would entail, such as studying all competing products, including those offered by compounding pharmacies. The entire process was simply designed to justify senior management's decision to acquire the drug in the first place at an excessive price. Indeed, the lack of market research into price led to heated discussions between CW1 and Defendant Goedeke regarding the exorbitantly high price of the drug. According to CW1, Defendant Goedeke dismissed his concerns, baselessly stating "we can charge whatever we want."

- Plaintiff is prepared to provided greater background information on all of the CWs in an amended pleading as well as several new CWs that will demonstrate the CWs had far greater experience and expertise in the area of pharmaceutical marketing, sales and pricing than did the members of K-V management who ignored their warnings and unilaterally made the pricing decision solely in hopes of driving up the price of K-V stock and inflating the asset value of K-V.

Plaintiff submits these additional facts not pleaded in the current Complaint, coupled with those already in the current Complaint, give rise to a strong inference of scienter on the part of Defendants with respect to their knowledge that K-V would not be able to halt the compounding

of Makena and that K-V, therefore, could not realize substantial economic returns from sales of the drug at the prices Defendants chose to charge. Thus, not only were Defendants warned by credible, highly experienced employees that the FDA would not enforce exclusivity at the prices K-V intended to charge for the drug, and that even if the FDA chose to enforce, FDA's enforcement would not effectively halt the compounding of the drug, but Defendants took action consistent with that knowledge by by-passing the FDA in a futile effort to halt compounding, which only had the effect of compelling the FDA to take the "unique" step of announcing its position that it would not enforce Makena's exclusivity. Neither of these substantial risks known to Defendants were ever adequately disclosed during the Class Period.[3] Taken together with all the other factual allegations of the Complaint, which must be accepted as true, and considered

[3] The Complaint alleges: that Defendant Goedeke was directly warned by CW1 that if the Company goes out with $1,500 per injection, "we will kill ourselves; we will absolutely fail"; that due to the pricing, "the FDA would not prevent compounding pharmacies from producing 17P"; "that the staggering price tag would destroy K-V's relationships with critical organizations"; and that such pricing "will have people in an uproar"; that the desire of Defendants Divis and Goedeke to have a $4 billion company (by charging $1,500 per injection) stopped them from "heeding the warnings from CW1"; and that CW1 informed Defendants Goedeke and Divis that "due to the sheer number of compounding pharmacies, it would not be fiscally possible for the FDA to police all the pharmacies." ¶¶11, 19, 49. *See Simon v. Abiomed, Inc.*, No. 12-12137, 2014 U.S. Dist. LEXIS 49727, at *59 (D. Mass. Apr. 10, 2014) (adopting a standard for evaluating scienter in a case involving undisputed off-label marketing of a medical device based on whether the defendants were warned by others of the omitted information) (citing *In re Boston Scientific Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012)). Here, there is no dispute that CW1 warned Defendants Goedeke and Divis of the dire consequences of their pricing decision. Nor is there any dispute that Defendants Goedeke and Divis never disclosed to K-V investors the specific risks warned of by CW1 when disclosing K-V's ability to enforce or obtain enforcement of its purported exclusivity or its pricing decision. Nor is there any dispute as to the validity of CW1's warnings of dire circumstances from Defendants' pricing decision – the Defendants' pricing decision got "people in an uproar," the FDA, in reaction to K-V's attempt to obtain exclusivity on its own by directly threatening compounding pharmacies with FDA action, affirmatively and very publicly announcing it would not enforce K-V's exclusive right to distribute hydroxyprogesterone caproate, and the pricing decision effectively "killed" the Company (forcing it ultimately to file for bankruptcy). Clearly K-V investors had a right to know what Defendants Goedeke and Divis knew – the risks associated with these warned-of, obviously material, risks and their potential adverse consequences related to the pricing of Makena announced on February 14, 2011.

holistically as required by the Supreme Court, Plaintiff submits she can provide an amended complaint that will survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6) and 9(b), and the Private Securities Litigation Reform Act of 1995.

I. LEGAL STANDARDS FOR RECONSIDERATION AND LEAVE TO AMEND

Rule 54(b) "permits the district court to 'exercise its general discretionary authority to review and revise its interlocutory rulings prior to the entry of final judgment.'" *Evans v. Contract Callers, Inc*., No. 4:10-2358, 2012 U.S. Dist. LEXIS 8573, at *5 (E.D. Mo. Jan. 25, 2012) (quoting *Auto Servs. Co. v. KPMG, LLP*, 537 F.3d 853, 856-57 (8th Cir. 2008)); *see also Partmar Corp. v. Paramount Pictures Theatres Corp*., 347 U.S. 89, 100 (1954) (observing that "[t]he power remained in the trial court until the entry of his final judgment to set aside, for appropriate reasons," orders previously entered in the case). "Although the precise standard for evaluating a motion to reconsider under Rule 54(b) is unclear, whether to grant such a motion rests within the discretion of the court." *De Olivera Dos Santos v. Bell Helicopter Textron, Inc. District*, 651 F. Supp. 2d 550, 553 (N.D. Tex. 2009).

The court "has greater discretion to grant a motion to reconsider an interlocutory order [under Rule 54(b)] than a motion to reconsider a motion brought pursuant to Rules 59(e) or 60(b)," *Disc. Tobacco Warehouse, Inc. v. Briggs Tobacco & Specialty Co*., No. 3:09-05078, 2010 U.S. Dist. LEXIS 91239, at *7 (W.D. Mo. Sept. 2, 2010), but "[g]enerally, courts will reconsider a decision if a party can show (1) new facts, (2) new law, or (3) clear error in the court's prior decision." *Labastida v. McNeil Techs., Inc*., No. 10-1690, 2011 U.S. Dist. LEXIS 18605, at *5 (S.D. Cal. Feb. 25, 2011).

A motion pursuant to Rule 54(b) is the proper method of seeking reconsideration here because the Order was not final. *See Jones v. Casey's Gen. Stores,* 551 F. Supp. 2d 848, 854

(S.D. Iowa 2008) (applying Rule 54(b) and finding "Rule 60 is inapplicable in the present situation, since the Court's March 20, 2008 Order was not a final order or judgment"); *Interstate Power Co. v. Kansas City Power & Light Co*., 992 F.2d 804, 807 (8th Cir. 1993) (reversing the district court's application of Rule 60(b) to motion for reconsideration of an order that was not a "final judgment, order, or proceeding," and holding the motion should have been decided pursuant to Rule 54(b)). As discussed herein, Plaintiff has obtained new facts which she believes, if permitted to plead, would suffice to state a claim under §10(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 promulgated thereunder.

There is also some *dicta* in Eighth Circuit cases suggesting that motions to reconsider "are nothing more than Rule 60(b) motions when directed at non-final orders." *Elder-Keep v. Aksamit*, 460 F.3d 979, 984 (8th Cir. 2006) (citing *Anderson v. Raymond Corp*., 340 F.3d 520, 525 (8th Cir. 2003) and *Broadway v. Norris*, 193 F.3d 987, 989 (8th Cir. 1999)). In the event this Court follows the *dicta* from the Eight Circuit cases referenced above, Plaintiff also seeks consideration pursuant to Rule 60(b). Rule 60(b) provides that on "motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for" a variety of reasons, including mistake, inadvertence, surprise, excusable neglect, and "any other reason that justifies relief." Rule 60(b)(6). To reiterate, the grounds for reconsideration are "(1) new facts, (2) new law, or (3) clear error in the court's prior decision." *Labastida*, 2011 U.S. Dist. LEXIS 18605, at *5.

Notably, those cases endorsing prejudgment reconsideration under Rule 60(b) have "been criticized for failing to recognize a district court's inherent authority to reconsider interlocutory orders, authority which as a practical matter a district court needs in order to modify orders in response to the changing circumstances of a lawsuit before it." *Disc. Tobacco Warehouse, Inc.*,

2010 U.S. Dist. LEXIS 91239, at *5-*6 (citing *Garrett v. Albright*, No. 4:06-4137, 2008 U.S. Dist. LEXIS 6908, at *8 (W.D. Mo. Jan. 30, 2008)). Thus, in any event, the Court retains the inherent discretion to reconsider any order before entry of a final judgment. Coupled with "the liberal amendment policy of Fed. R. Civ. P. 15(a), permitting Plaintiff to amend with respect to the broader issues discussed herein is appropriate. Indeed, a district court's denial of leave to amend pleadings is appropriate only in those limited circumstances in which undue delay, bad faith on the part of the moving party, futility of the amendment, or unfair prejudice to the non-moving party can be demonstrated." *Roberson v. Hayti Police Dep't*, 241 F.3d 992, 995 (8th Cir. 2001).[4] Here, Plaintiff has put before the Court new facts that she believes if they had been alleged in the Complaint would, with the other allegations of the Complaint, suffice to adequately plead falsity and scienter. *See Boparai v. Shinseki*, No. 1:12-00789, 2013 U.S. Dist. LEXIS 36230, at *1 (E.D. Cal. Mar. 14, 2013) (granting leave to amend his complaint where plaintiff asserted new facts to support his claims) (citing *Lopez v. Smith*, 203 F.3d 1122, 1127-28 (9th Cir. 2000)); *Edwards v. Duane, Morris & Heckscher LLP*, No. 01-4798, 2004 U.S. Dist. LEXIS 24177, at *32 (E.D. Pa. Nov. 29, 2004) ("Rule 15(a) is meant to apply to precisely the circumstances that exist here – to amend pleadings when new facts are discovered.").[5]

II. PLAINTIFF SHOULD BE PERMITTED TO AMEND REGARDING

[4] Presumably, by the Court granting leave to amend one portion of the Complaint, it was not concerned with an amended complaint causing undue delay or prejudice. Likewise, allowing Plaintiff an additional 20 days to amend on a wider scope will likewise not cause any undue delay or prejudice.

[5] *See also Eminence Cap., LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052-53 (9th Cir. 2003) (reversing district court's denial of leave to amend even though defendants claimed that plaintiffs already had "three bites at the apple"); *Constr. Laborers Pension Trust v. Neurocrine Biosciences, Inc.*, No. 07-1152, 2008 U.S. Dist. LEXIS 78290, at *15-*16 (S.D. Cal. Sept. 23, 2008) (granting a third opportunity to amend a complaint in light of the heightened pleading standards required of securities fraud cases); *Martino-Catt v. E.I. Dupont De Nemours & Co.*, 213 F.R.D. 308, 323 (D. Iowa 2002) ("leave to amend a complaint is to be liberally granted, particularly in cases alleging fraud.").

DEFENDANTS' STATEMENTS CONCERNING EXCLUSIVITY AND MARKET RESEARCH TO DEMONSTRATE THEY WERE MATERIALLY FALSE AND MISLEADING AND MADE WITH SCIENTER

A. Plaintiff Has New Information Supporting the Falsity of Defendants' Statements Concerning the Exclusivity of Makena

Plaintiff previously alleged that Defendant Goedeke's statements that "[W]e believe that the regulations and laws are very clear. . . . FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products that are the same or essentially the same as FDA-approved products" and "[w]e also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them" were materially false and misleading when made. Plaintiff alleged that Defendant Goedeke had no reasonable basis for stating that FDA regulations would prohibit compounding pharmacies from distributing the drug. The Complaint also alleged that Goedeke had no reasonable basis for stating a belief that such pharmacies would, as a result of the threat of enforcement of such regulations, not compound and distribute the drug. ¶¶48-49. CW1 personally discussed with Defendants Goedeke and Divis prior to the announcement of Makena's $1,500 per dose price that the FDA would not preclude compounding pharmacies from producing the drug. ¶¶11, 19, 49. Further, CW1 informed Defendants Goedeke and Divis that "due to the sheer number of compounding pharmacies, it would not be fiscally possible for the FDA to police all the pharmacies." ¶49.

The Complaint described how, despite the foregoing, Defendants nevertheless issued letters on February 17, 2011 to compounding pharmacists stating that "compounded, unapproved formulations of hydroxyprogesterone caproate injection should no longer be made by compounding pharmacies," and that FDA enforcement "discretion does not extend to compounding of copies or essentially copies of commercially available FDA-approved products." ¶50. The Complaint further described how, approximately two months later on

March 30, 2011, the FDA informed K-V (and the rest of the world), *via* a press release, that its statements that the FDA would take enforcement action against compounding pharmacies were "not correct." ¶¶51, 63.

The Court dismissed these allegations concerning exclusivity, finding Plaintiff had failed to plead the requisite strong inference of Defendants' scienter. Order at 22. Plaintiff respectfully requests that the Court reconsider its denial of leave to amend these allegations.

1. New Facts Suggest K-V Sent Letters to Compounding Pharmacies Because Defendants Knew the FDA Would Not Enforce Exclusivity

K-V's unilateral direct mailing of letters to compounding pharmacies stating that "compounded, unapproved formulations of hydroxyprogesterone caproate injection should no longer be made by compounding pharmacies" and "discretion does not extend to compounding of copies or essentially copies of commercially available FDA-approved products" was, in fact, conduct amounting to an admission that it knew or was substantially certain that if it asked the FDA to enforce, the FDA would have refused to do so. This provides strong evidence of Defendants' knowledge that there was a very substantial risk that the FDA would not enforce Makena's exclusivity, and that even if the FDA did so, it could not effectively stop pharmacies from compounding the drugs because of its limited resources. Ordinarily, standard operating procedure is for the FDA, after being notified of a violation by the company with the ODA status, to send warning letters to entity or entities that violate the ODA. This was the case with Premarin, where the FDA initiated an enforcement action against pharmacies compounding

menopausal hormone therapy drugs.[6]

Since dismissal, after further communications with CW1, s/he has confirmed his/her previous statements that s/he told Defendant Goedeke that, based on his/her past experience and knowledge as a 30-year veteran of the pharmaceutical industry,[7] that the FDA would not prevent compounding pharmacies from making the drug, and, even if they tried, such enforcement would be ineffective. Further, as CW3, who was a Government Pricing Manager at K-V from 2005 to 2009, ¶2, has confirmed in communications following dismissal, by sending letters directly to compounding pharmacies, K-V was deliberately alienating itself from the FDA by usurping the agency's authority and jurisdiction. Such a treacherous course of action only makes sense if Defendants already knew there was a very strong likelihood that the FDA would not enforce Makena's exclusivity. Indeed, if a reasonable person believed a federal governmental enforcement agency would enforce its rights against third parties, why would that person write its own letter to the offending persons? Clearly a communication from the applicable federal

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[6] *See also* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm165587.htm (FDA sent warning letters to compounders of morphine sulfate; "The Food and Drug Administration (FDA) has sent warning letters directing companies to stop making and distributing specific narcotic products in certain dosage forms that lack the required FDA approval. Affected products include unapproved high concentrate oral solutions containing morphine sulfate and unapproved immediate release tablets containing morphine sulfate, hydromorphone, or oxycodone."); http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm183088.htm ("FDA issued several Warning Letters today notifying certain compounding pharmacies about unlawful practices related to their compounded 'BHRT' drugs. FDA's letters warned the pharmacies that they make false and misleading claims about their 'BHRT' drugs, including claims that compounded 'BHRT' drugs are safer or more effective than FDA approved hormone therapy drugs and claims that compounded 'BHRT' drugs can prevent or treat serious illnesses such as Alzheimer's disease and certain forms of cancer. In addition, FDA warned a number of pharmacies that they may not compound drugs containing the estrogen substance estriol without a valid investigational new drug application. Firms that do not properly address violations identified in Warning Letters risk further enforcement, including injunctions that prevent additional violations and seizure of violative drugs.").

[7] CW1's specialties include market analysis and business development.

governmental enforcement agency would have a much greater impact. The most plausible explanation is that K-V wrote its own letters because, unbeknownst to K-V investors, Defendants did not believe the FDA would act on K-V's behalf or knew that there was substantial risk the FDA would not do so.

CW3 further explained that, even if the FDA initiated efforts to enforce K-V's exclusivity, such efforts were unlikely to be successful because the backlash against unpopular enforcement actions like Morphine had made the agency reluctant to take steps like shutting down compounding pharmacies. Indeed, CW1 who had witnessed the Premarin enforcement action while at Wyeth, specifically warned Defendants Goedeke and Divis that any such action would be unsuccessful for this same reason. CW1 explained to them how Wyeth (a corporation many times larger, more powerful and wealthier than K-V) had sought to have compounding pharmacies shut down, and had convinced the FDA to send warning letters, which letters were ineffective in stopping compounding pharmacies. It is a compelling inference that in recognition of, and in an effort to counter, the risks CW1 argued K-V's aggressive pricing created, K-V sent the letters directly to compounding pharmacies because they knew or were substantially certain the FDA would not, or could not effectively, enforce K-V's exclusively.

2. Defendants Have Now Conceded It Was Not and Is Not Clear That The FDA Regulations Would Be Enforced To Prohibit Pharmacies From Compounding Generic Makena

On February 10, 2014, Defendants filed the Notice wherein they brought to the Court's attention the D.C. Circuit's *K-V Pharmaceutical Co. v. FDA, et al.*, No. 12-5349 (D.C. Cir.), filed on February 10, 2014, which vacated a district court's dismissal and remanded for reconsideration in light of *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) and the Drug Quality and

Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013).[8] Although Defendants, in their motion to dismiss, argued that their statements regarding exclusivity were not false and misleading because "K-V accurately summarized the law and FDA policy up until that time" and that no facts were pled to show that Defendants did not "genuinely or reasonably believe that compounding pharmacies would follow the law," Def. MTD, Dkt. No. 91, at 16-17, in the Notice, Defendants conceded that "[w]hether and to what extent the FDA had the discretion not to enforce exclusivity under the Orphan Drug Act remains a matter of ongoing dispute in the D.C. District Court Action." Notice at 1. This concession defeats all of Defendants' non-culpable explanations for their Class Period statements that they "believe[d] that ***the regulations and laws are very clear***. . . . FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products," and that "we also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them." ¶¶17-19, 48, 50 (emphasis added). Clearly, the FDA does not agree with K-V's alleged view of the regulations and the law. And, based on K-V's admission in its Notice, all that is now clear is that the regulations and the law with respect to enforcement of an orphan drug owner's exclusivity are unclear and a matter of intense uncertainty and dispute. This is a far cry from Defendants' affirmative assurances to securities analysts on February 14, 2011, in response to questions about how K-V would stop compounding pharmacies, that the law and regulations

[8] It bears emphasis that, as with any dispositive motion that assesses the sufficiency of the complaint, the Court "generally must ignore materials outside the pleadings with certain very narrow exceptions. *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999) (citations omitted). While the Court may take judicial notice of materials that are part of the public record or do not contradict the complaint, *id.*, the documents may only be considered to show their contents, not to prove the truth of matters asserted therein," *Tal v. Hogan*, 453 F.3d 1244, 1265 n.24 (10th Cir. 2006). Accordingly, the Court could not previously consider any facts Plaintiff or Defendants may have proffered at the hearing on the motion to dismiss, or in any of their briefs, because such information would, by definition, be beyond the scope of the complaint. Thus, these would be new allegations in an amended complaint.

would enable K-V to stop compounders competing with it. Simply, the statements quoted above were intended (and did) mislead investors about the value of Makena and, in turn, K-V stock.

And even if the courts ultimately decide Defendants are correct that the FDA is obligated to enforce K-V's exclusivity, Defendants' statements during the Class Period were still materially false and misleading at the time they were made by Defendants because Defendants' unreasonable, one-sided description of K-V's ability to exploit Makena's ODA status failed and omitted to disclose the specific substantial risks they were warned about by highly experienced employees of K-V regarding the likelihood that the FDA would not enforce exclusivity and, alternately, the impracticality and unlikely effectiveness of any attempt at comprehensive enforcement of such exclusivity. At best, this was the very definition of severe recklessness for the purposes of scienter. *See Elam v. Neidorff*, 544 F.3d 921, 928 (8th Cir. 2008).

B. New Facts Demonstrating That Defendants' Statements Concerning the Extent of Their Market Research To Price Makena Were Materially False and Misleading

In the conference call with investment analysts, on February 14, 2011, Defendants represented that "we believe our pricing approach is supported by a very comprehensive market research plan which included all stakeholders." Order at 5. New information from the CWs, however, establishes that Defendants' claims were materially false and misleading. Indeed, CW1 now reports that K-V conducted virtually no marketing research into pricing. The lack of market research into price led to heated discussions between CW1 and Defendant Goedeke regarding the high price of the drug. According to CW1, Defendant Goedeke dismissed his concerns, insisting, without a reasonable basis in fact, that "we can charge whatever we want."

CW3, who was an expert in pricing, confirms this account. CW3 reports, based on his/her personal knowledge, that K-V did none of the things a full market analysis would entail, such as studying all competing products, including those by compounding pharmacies. The

entire process was simply designed to rationalize senior management's decision to acquire the drug. According to this CW, Defendant McHugh knew no market research was performed, and the CW3 described the failure do these things as "willful blindness."

Plaintiff respectfully submits these CW accounts establish not only that Defendants' statements that K-V had conducted "very comprehensive" market research "which included all stakeholders," which Defendants offered to respond to securities analysts' questions and allay their concerns about the high price of Makena and the effect the price would have on sales, were materially false and misleading, by that they were made by Defendants when no such "very comprehensive" market research had been done. By definition, that constitutes a false and misleading statement made with scienter.

CONCLUSION

Based on the foregoing, the Court should reconsider the scope of the leave to amend, and allow Plaintiff to file an amended complaint alleging the new information described herein within 20 days.

Dated: April 16, 2014

HOLLAND, GROVES, SCHNELLER
& STOLZE, LLC

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CERTIFICATE OF SERVICE

I hereby certify that on April 16, 2014, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the email addresses denoted on the Court's electronic mail notice list.

/s/ Eric D. Holland
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